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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,173	12/16/2005	Philippe Msika	065691-0423	1955
22428 7590 04/15/2008 FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007				
EXAMINER				
JAVANMARD, SAHAR				
ART UNIT		PAPER NUMBER		
1617				
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04/15/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/561,173

Applicant(s)

MSIKA ET AL.

Examiner

SAHAR JAVANMARD

Art Unit

1617

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-31 is/are pending in the application.
- 4a) Of the above claim(s) 15,22-27,30 and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14,16-21,28 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB-08)
- Paper No(s)/Mail Date 12/16/05; 5/2/06
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Claims

This Office Action is in response to applicant's remarks filed on 2/1/2008.

Claim(s) 14-31 are pending. Claim(s) 15, 22-27, 30 and 31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant's election without traverse of the restriction requirement drawn to Group I and election of OX100 as the species in the reply is acknowledged. The requirement is deemed proper and is therefore made FINAL. Claim(s) 14, 16-21, 28 and 29 are examined herein insofar as they read on the elected invention and species.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14, 16, 19-21, 28 and 29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabling for oxazoline compound OX100, does not reasonably provide enablement for the promotion of slimming with any oxazoline compound as set forth in the instant claims. The specification does not provide sufficient information that all oxazoline compounds are capable of promoting

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slimming. Thus, the term "oxazoline" is very broad as cited in claims 14, 16, 19-21, 28 and 29.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The specification does not provide sufficient information that all oxazoline compounds are capable of promoting slimming.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApl 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1). The Nature of the Invention:

All of the rejected claims are drawn to an invention which pertains to a method of promoting slimming with the administration of an oxazoline compound as described in claims 14, 16, 19-21, 28 and 29. The nature of the invention is complex in

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that it encompasses the treatment said ailments using a wide array of compounds encompassed by the term "oxazoline".

(2). Breadth of the Claims:

The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The claims encompass methods of promoting slimming by administering by a wide array of compounds encompassed the term "oxazoline". There are countless possible compounds encompassed by "oxazoline" for the treatments claimed. The general definition "oxazoline" used in the claims of the present application does not clearly define any chemical. If there is support for the specific oxazoline compounds, the claims must be limited as such. The claims are therefore much broader than the enabling disclosure.

(3). Guidance of the Specification:

The guidance given by the specification as to how effective the disclosed oxazoline compounds are at treating the desired ailments is limited. A series of assays are run to evaluate lipid synthesis in adipocytes in suspension.

(4). Working Examples:

Applicant only provides testing results for OX100.

(5). State of the Prior Art:

The state of the prior art regarding oxazolines in cosmetic applications is limited.

(6). Nature and predictability of the invention

The nature of the invention is directed towards medicine and is therefore physiological in nature. It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

(7). The Quantity of Experimentation Necessary:

In order to practice the claimed invention, one of skill in the art would have to first envision a combination of an appropriate pharmaceutical carrier, a dosage for each compound as encompassed by "oxazoline", the duration of treatment, route of treatment, etc. and, in the case of human treatment, an appropriate animal model system for one of the claimed compounds. One would then need to test the combination in the model system to determine whether or not the combination is effective for promoting slimming. If unsuccessful, which is likely given the lack of significant guidance from the specification or prior art regarding promotion of slimming with any oxazoline compound, one of skill in the art would have to then either envision a modification of the first combination of pharmaceutical compound, compound dosage, duration of treatment, etc. and appropriate animal model system, or envision an entirely new combination of the above and test the system again. Therefore, it would require

undue, unpredictable experimentation to practice the claimed invention to promote slimming by administration of one of the oxazoline compounds as set forth in the claims.

Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, methods of promoting slimming by applying the various oxazoline compounds of the claims is not considered to be enabled by the instant specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 14, 16-21, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rajadhyaksha et al. (US Patent No. 4,876,249) in view of Wamper (US Patent No. 2,368,075).

Rajadhyaksha teaches compositions for carrying physiologically active agents through body membranes such as skin and for retaining these agents in the body tissues and further relates to a method of administering systemically active agents through the skin or other body membranes of humans and animals, utilizing a transdermal device or formulation, containing an effective, non-toxic amount of a membrane penetration enhancer having the structural formula I (column 3, lines 23-32), namely OX100 (column 15, example 11).

Rajadhyaksha teaches that agents for topical applications include among a list of agents, vasodilators and collagen softening agents (column 12, lines 10-20).

Further Rajadhyaksha teaches that the amount of oxazoline for enhancing percutaneous absorption topically ranges between 0.01 to about 10% preferably 0.1 to 5% by weight of the composition.

Rajadhyaksha does not teach the oxazolines as promoting slimming.

Wamper teaches a number of oxazolines including 2-hendecyl-4,4-dimethyloxazole (a.k.a. 2-undecyl-4,4-dimethyl-1,3-oxazoline) (page 1, right column, lines 22-46) in cosmetic preparations as astringents.

According to Stedman's medical dictionary, an "astringent" is an agent that causes contraction or shrinkage of the tissues.

It would have been obvious to one of ordinary skill in the art at the time of the invention to have employed the oxazoline-containing topical formulations taught by Rajadhyaksha for use in promoting slimming. The motivation is provided by Wamper. Wamper teaches that oxazolines act as astringents in cosmetic applications. Thus, one would expect, with a reasonable degree of certainty, that oxazoline-containing topical formulations can be used to promote slimming.

Conclusion

Claims 14, 16-21, 28, and 29 are not allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sahar Javanmard whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/S. J./

Examiner, Art Unit 1617

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617

